Research
Conflicts of Interest
at Boston University

Jodi R. Edelstein, JD
Compliance Manager, COI Unit
Office of Research Compliance
Outline

• BU Policies
• Investigator responsibilities
• Metrics and statistics at BU
## BU FCOI Policies – Based on Sponsor

<table>
<thead>
<tr>
<th>BU General Policy (October 31, 2003)</th>
<th>BU PHS Addendum (August 24, 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on 1995 PHS and NSF federal regulations</td>
<td>Based on 2011/2012 PHS federal regulations Covering BU grants sponsored by:</td>
</tr>
</tbody>
</table>
| Covering grants at BU proposed for funding by all sponsors not listed in the other column, including unfunded/departmentally funded human subjects research | **Public Health Service (PHS) Agencies**  
OG, OASH, ASPR, AHRQ, ATSDR, CDC, FDA, HRSA, HIS, NIH, SAMHSA  
**Non-PHS Agencies**  
Alliance for Lupus Research (ALR)  
American Asthma Foundation  
American Cancer Society (ACS)  
American Heart Association (AHA)  
American Lung Association (ALA)  
Arthritis Foundation (AF)  
Juvenile Diabetes Research Foundation (JDRF)  
Lupus Foundation of America (LFA)  
Susan G. Komen for the Cure  
CurePSP |
# Investigator Disclosures Under Each Policy Scheme

<table>
<thead>
<tr>
<th></th>
<th><strong>BU General Policy</strong></th>
<th><strong>BU Addendum</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disclosures</strong></td>
<td>Only SFIs that investigator determines could affect research</td>
<td>All SFIs that investigator determines are related to institutional responsibilities</td>
</tr>
<tr>
<td><strong>Threshold</strong></td>
<td>Salary, Royalties, Consulting, Patent and Copyright payments: $10k – look forward 12 months</td>
<td>Salary, Royalties, Consulting, Patent and Copyright payments): $5k – look back 12 months</td>
</tr>
<tr>
<td></td>
<td>Equity: No thresholds</td>
<td>Equity: $5k for publicly traded entities – no threshold for privately held entities</td>
</tr>
<tr>
<td><strong>Travel</strong></td>
<td>Not explicitly covered</td>
<td>Included over $5k</td>
</tr>
<tr>
<td><strong>Exclusion of</strong></td>
<td>Excluded if sponsored by any public or non-profit entity</td>
<td>Excluded if sponsored by government, university, or medical center</td>
</tr>
<tr>
<td>income from</td>
<td></td>
<td></td>
</tr>
<tr>
<td>seminars,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>lectures,</td>
<td></td>
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<tr>
<td>advisory</td>
<td></td>
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<tr>
<td>committees,</td>
<td></td>
<td></td>
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<tr>
<td>review panels</td>
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</tbody>
</table>
## Additional Policy Differences

<table>
<thead>
<tr>
<th></th>
<th>BU General Policy</th>
<th>BU Addendum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Investigator Disclosure?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Investigator Training</td>
<td>Not covered</td>
<td>Every 4 years</td>
</tr>
<tr>
<td>Public Accessibility (providing info on request)</td>
<td>Not covered</td>
<td>Website or must provide certain info on FCOIs of senior personnel on request</td>
</tr>
</tbody>
</table>
Investigator Responsibilities

- Financial Interest Disclosure Training (under “BU Addendum” only)
  - On investigator policy responsibilities
  - Once every 4 years while engaged in research
  - Via Blackboard Learn
  - Email is sent from coi@bu.edu if training is needed

- Disclose
  - Financial interests related to your professional responsibilities at BU
  - Prior to grant submission, annually during the award, update within 30 days of newly acquired/discovered interest
  - Online or using “paper” Adobe/Word form (both at bu.edu/orc/)

There are no special responsibilities for BU leadership.
How to Train

• Get a BU username
  • https://www.bu.edu/link/bin/uiscgi_research_compliance.pl
• Get a Blackboard Learn account
  • https://learn.bu.edu
• Search for “Financial Interest Disclosure Training”
• Get a score of 80
How to Disclose

• Go to https://share.bu.edu/sites/fcoi/
• Grant admins pre-fill form for PIs (optional)
• PIs get email; disclose
• Investigators get email; disclose
  • “investigators” = all those responsible for design, conduct and research of project, including senior/key personnel at minimum

For more info:
Go to http://www.bu.edu/orc/forms/coi/
Financial Interest Disclosure Module

For All Investigators (including pending forms):
  My Financial Disclosure Forms

For Principal Investigators only:
  View Submission Status

For Grant Administrators only:
  Manage Projects
Troubleshooting

- coi@bu.edu
- 617-414-4751
- Go to http://www.bu.edu/orc/forms/coi/
- When not connected to BU network, your User Name is your BU email address (e.g., jedelste@bu.edu instead of jedelste)
Metrics

Important Dates:

**August 2012**  New policy implemented (BU Addendum)
**March 2013**  Birth of FIDDLE
               (Financial Interest Disclosure Database Limited Ed.)
**November 2013**  New online disclosure system was launched

Data Set:

The COI Unit in the Office of Research Compliance handles disclosures for research at BU and BMC. These numbers encompass both.
FIDDLE

RESEARCH PROJECT DETAILS

Project Track: Disclosures - Training - SFI - Internal - FCOI - Committee - Management

- Disclosures Needed
- Training Needed
- SFI Discovered
- Internal Discovered
- FCOI Discovered
- Committee Review Scheduled
- Management Plan Drafting
- Management Plan Finalizing
- All CLEAR

Governing Policy: RU-PHS-FINDI

Project ID: 4109

OSF/OGA Admin: Goodridge B.P. Y.MED

Funding Stage: Proposal

Award/Contr. #: 

Budget: 

Data Awarded: 

Human Subjects: Yes

Special Designations:
- STTR Phase 1
- SBIR Phase 1
- Pre-Clinical
- Clinical Study/Demo
- IND or IDE
- None of Above

Pending:

Compliance Status: All Clear

Project Personnel:

User: 

Surname: First Name: Project Role: Train Date: Grade: F1Submit: F2Submit: FormsClear:


White, PhD: Laura Forsberg: Biostatistician: 11/13/2012: 100: 11/12/2013

Yu: Jeffrey: Data Analyst: 10/5/2012: 90: 11/12/2013

Project Status Log:

Status Date: 11/12/2013 12:43:33 PM

Classification: All Clear

Status Notes:

Double Click to Edit Disclosure

View Investigator's Yeses

Open New Case

Save Close

Project Creator: chapman
Disclosure Module Announcement

Boston University Research Compliance

TO: Research Community
FROM: Kate Mellouk, Associate Vice President, Research Compliance
DATE: January 9, 2015
SUBJECT: New and Improved: Financial Interest Disclosure Module

Dear Colleagues:

We are pleased to announce a new and improved financial interest disclosure module that enhances the online module Boston University and Boston Medical Center have been using for the past year as we transition away from the paper disclosure process in research compliance.

To reduce paperwork burden and save valuable investigator time, this module will:

- Allow grant administrators to pre-fill project information for principal investigators;
- Save and pre-fill prior disclosed financial interests;
- Serve as a holding place for all financial interest disclosures submitted through the module; and
- Allow grant administrators and PIs to track when disclosure forms are completed by the other investigators in the project.

Should you need any assistance, we are here to help.
Call: Andre Chapman (617) 414-4751
Email: coi@bu.edu
Quick Tips

Reminder: A BU username is required to disclose. You can electronically request a BU username here.

We are working hard to continuously improve and help increase efficiencies within the Research Compliance areas. If you have any additional feedback, please feel free to email coi@bu.edu or email me directly.
Disclosures per Administering Office

- **MED - OSP**: 43%
- **CRC-OSP**: 29%
- **BMC - OGA**: 24%
- **Unknown/Other**: 4%
Principal Investigators per Medical Campus Department (1/20/15)

1) Pediatrics
2) General Internal Medicine
3) Psychiatry
4) Biochemistry
5) Neurology
6) Infectious Disease Medicine
7) Endocrinology, Diabetes & Nutrition
8) Anatomy & Neurobiology
9) Pulmonary Center
10) Pharmacology & Experimental Therapeutics
Total # of Disclosures per Month | Time to File by Coordinator

<table>
<thead>
<tr>
<th>Month</th>
<th>Disclosures</th>
<th>Days to file by Coordinator - Average</th>
<th>Days to file by Coordinator - Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2013</td>
<td>541</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>January 2014</td>
<td>652</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>February 2014</td>
<td>567</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>March 2014</td>
<td>691</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>April 2014</td>
<td>684</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>May 2014</td>
<td>805</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>June 2014</td>
<td>1073</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>July 2014</td>
<td>939</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>August 2014</td>
<td>613</td>
<td>0</td>
<td>0.053</td>
</tr>
<tr>
<td>September 2014</td>
<td>686</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>October 2014</td>
<td>681</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>November 2014</td>
<td>592</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>December 2014</td>
<td>670</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Average = 707
% Online Disclosures (versus paper), by Month
% Affirmative Disclosures per Month

Average = 7.7%
Average = 87.3% all clear at continuation
Also, December 2014: 75% of New Awards had “All Clear” by Project Start
Reasons Affirmative Disclosures Were Not FCOIs

1. Unrelated to Project
2. Under SFI Threshold
3. Policy Exception
3232 total recorded scores (1/20/15)

80 is a passing score
FCOI Faculty Committee Caseload

- Number of Cases Reviewed by Committee
- Number of Cases Received a Management Plan form the Committee
Thank you!

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and Boston Medical Center
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(617) 638-4514